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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,395	11/10/2003	Wolfgang Muller	MAN-012	4405

28661 7590 07/18/2005

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,395	MULLER ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *3 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602. The title of the invention is omitted.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Radio Frequency Ablation Probe."

The disclosure is objected to because of the following informalities:

On page 1, line 17, there is a prohibited reference to a claim in the specification. Since claims may be amended or dropped in the course of the application prosecution, references to claims in the specification are not allowed.

On page 8, line 16, there appears to be a typographical error wherein "patient" is misspelled as "patent." As it stands, the meaning is unclear.

Appropriate correction is required.

Drawings

The drawings are objected to because 10 and 12 in Fig. 1 are not illustrative of a "radio frequency generator" and a "neutral electrode," respectively. It is suggested that

they be labeled as such. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 3 is objected to because of the following informalities: Alternative expressions using "or" are acceptable in the claims. See MPEP § 2173.05(h). However, the claim would be clearer if it were made to read: "*one* of spiral shape, zig-zag shape, wave shape, or meander shape."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser, et al. (U.S. Pat. No. 5,313,943).

Regarding claim 1, Houser, et al. disclose an expandable ablation catheter usable with radio frequency energy. It includes a flexible catheter 18 that is also inherently an insulating hose since it is an ablation catheter (Fig. 1). At the distal end, there is a three dimensional array of electrodes 22 (Fig.1) made of a conductive metal such as platinum (col. 7, ln. 38). The electrode is changeable from a cylindrical shape (Fig. 4) to a star shape (Fig. 5). The electrode is formed by a plurality of flexible splines 76 (col. 7, ln. 11 and Fig 12) whose distal and proximal ends are connected to one another (Fig. 26), with the distal and/or proximal ends of the splines connected with electrical leads 24 (Fig. 1) to an RF control unit (col. 4, ln. 28-31).

Regarding claim 2, Houser, et al. disclose an electrode in accordance with claim 1 whose shape of an arm differs approximately at its center from its shape at both ends (Figs. 26).

Regarding claim 3, Houser, et al. disclose an electrode in accordance with claim 1 whose outer contour of an arm, interpreted as the outer edge of an arm, is wave-shaped approximately at its center and is straight at its two ends (Fig. 26). The claim language, "of spiral shape, zig-zag shape, wave shape, or meander shape," is interpreted to mean that only one such approximate configuration is necessary.

Regarding claim 4, Houser, et al. disclose an electrode in accordance with claim 1 whose distal and proximal ends of the arms are adjustable relative to one another with the aid of an actuation device provided at a proximal region of the catheter. The actuation device comprises a proximal actuator 34 with a steering member 50 along track 52 that is connected to the control wire 78 whose distal end is attached to the distal ends of the electrode arms (Fig. 7). The steering member 50 moves the distal and proximal ends of the arms relative to one another to expand and collapse the electrode from a cylindrical shape to a star shape (Figs. 4 and 5).

Regarding claim 5, Houser, et al. disclose an electrode in accordance with claim 1 whose proximal ends of the arms are connected to a flexible cannula 62 which is guided inside a hose 68 (Fig. 12).

Regarding claim 6, Houser, et al. disclose an electrode in accordance with claim 1 whose distal ends of the arms are connected to a flexible adjustment element 240 which is guided inside a hose 68 (Fig. 12).

Regarding claim 8, Houser, et al. disclose an electrode in accordance with claim 1 whose proximal end is provided with a connection 242 for flushing liquid (col. 19, ln. 43-44 and Fig. 26).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele (U.S. Pat. No. 5,860,974)

Regarding claim 1, Abele discloses an expandable radio frequency ablation catheter. It includes a catheter shaft 10 (Fig. 1) that is inherently an insulating hose since it is an ablation catheter. At the distal end, a "spiral cage" electrode made of "heat

conductive, electrically conductive wires" is provided (col. 4, ln 5-7). This description of the electrode is inclusive of a metal material. In addition, the electrode is changeable from a cylindrical shape (Fig. 12) to a star shape (Fig. 13). Star-shaped is interpreted as a structure with appendages radiating from a central point from an end-on view. The electrode is formed by a plurality of "flexible members" 72 whose distal and proximal ends are connected to one another (Figs. 12 and 13), with the distal and/or proximal ends of the members electrically connected with a wire 30 that connects to a cable 33 coupled to an RF control unit (Figs. 1 and 2).

Regarding claim 2, Abele discloses an electrode in accordance with claim 1 whose shape of an arm differs approximately at its center from its shape at both ends (Figs. 12).

Regarding claim 3, Abele discloses an electrode in accordance with claim 1 whose outer contour of an arm, interpreted as the outer edge of an arm, is wave-shaped approximately at its center and is straight at its two ends (Fig. 12). The claim language, "of spiral shape, zig-zag shape, wave shape, or meander shape," is interpreted to mean that only one such approximate configuration is necessary.

Regarding claim 4, Abele discloses an electrode in accordance with claim 1 whose distal and proximal ends of the arms are adjustable relative to one another with the aid of an actuation device provided at a proximal region of the catheter. The actuation device of Abele comprises a proximal actuator 14 (Fig. 1) connected to a tensioning wire (col. 7, ln. 49) that extends and retracts the inner catheter segment 76 to

adjust the distal and proximal ends of the arms from a cylindrical shape to a star shape (Figs. 12 and 13).

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Imran (U.S. Pat. No. 5,156,151).

Imran discloses a radio frequency ablation catheter probe in accordance with claim 1. There is an insulating hose 36 made of plastic (col. 3, ln. 28-30 and Fig. 1) at whose distal end a metal electrode 68 (Fig. 7) is provided whose spatial extent is changeable from a cylindrical shape 46 (Fig. 1) into a star shape (Fig. 12). The metal electrode is formed by a plurality of flexible arms 47 whose distal and proximal ends are connected to one another (Figs. 2, 11 and 12). Finally, the distal and/or proximal ends of the arms are electrically connected via leads 71 and cable 28 (Fig. 1) to a terminal for the supply of radio frequency current 196 (Fig. 10).

Regarding claim 9, the electrode is manufactured by introducing micro-cuts 56 (col. 3, ln. 60-64 and Fig. 2) into an areal blank 51 (Fig. 2) of electrically conductive material (col. 4, ln. 3-4 and 59-61). The micro-cuts 56 extend parallel to one another and in each case not extending up to the rim of the blank at their ends (col. 3, ln. 61 and 64-68 and Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele in view of Houser, et al.

Regarding claim 5, Abele teaches an electrode in accordance with claim 1 whose proximal ends of the arms are connected to a flexible cannula 70 (Fig. 12). The claim differs from Abele in calling for the cannula to be guided inside a hose. Houser, et al., however, disclose an electrode in accordance with claim 1 whose proximal ends of the arms are connected to a flexible cannula 62 which is guided inside a hose 68 (Fig. 12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Abele to guide the flexible cannula inside a hose in view of the teachings of Houser, et al. in order to keep the electrode free of detrimental tissue buildup and blood en route to the desired ablation site.

Regarding claim 6, Abele teaches an electrode in accordance with claim 1 whose distal ends of the arms are connected to a flexible adjustment element 76 (Fig. 12). The claim differs from Abele in calling for the flexible adjustment element to be guided inside a hose. Houser, et al., however, disclose an electrode in accordance with claim 1 whose distal ends of the arms are connected to a flexible adjustment element 240 which is

guided inside a hose 68 (Fig. 12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Abele to guide the flexible adjustment element inside a hose in view of the teachings of Houser, et al. in order to keep the electrode free of detrimental tissue buildup and blood en route to the desired ablation site.

Regarding claim 8, Abele teaches an electrode in accordance with claim 1 which includes a fluid dispensing lumen 97 as a part of the catheter for the purpose of augmenting the ablation effect at the tissue (col. 8, ln. 33-35 and Fig. 27). This is coupled with a fluid dispenser at the proximal end of the catheter that feeds into the dispensing port 95 (col. 8, ln. 38-40 and Fig. 27). The claim differs from Abele in calling for a connection for flushing liquid and not electrically conductive liquid.

Houser, et al. however, disclose an electrode in accordance with claim 1 whose proximal end is provided with a connection 242 for flushing liquid (col. 19, ln. 43-44 and Fig. 26). Given that the fluid types of Abele and Houser, et al. are analogous because both are designed to strengthen the ablation effect, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Abele to include flushing liquid in view of the teachings of Houser, et al. in order to strengthen the ablation effect using either flushing liquid or electrically conductive liquid.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser, et al. in view of Tu, et al. (U.S. Pat. No. 6,306,133 B1).

Houser teaches an electrode in accordance with claim 1 and that one or more electrodes can be located at the distal end of the electrode arms 74 for additional signal

measuring capability (col. 6, ln. 66-68 and Fig. 26). The claim differs from Houser, et al. in calling for the sensor specifically to be a temperature sensor. Tu, et al., however, discloses a radio frequency ablation probe with a temperature sensor 27 adjacent to the distal end of the electrode needle (Fig. 6). The addition of a temperature sensor is advantageous because it allows the radio frequency output to be precisely controlled to obtain the desired temperature for treating a tissue (col. 4, ln. 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal sensor of Houser, et al. to be a temperature sensor in view of the teachings of Tu, et al. for the advantage of precisely controlling the radio frequency output to obtain the desired temperature for treating a tissue.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abele in view of Tu, et al.

Abele teaches an electrode in accordance with claim 1 and that a sensing electrode may be located at the distal end of the electrode arms 76 (col. 7, ln. 44-45, and Fig. 13). The claim differs from Abele in calling for the sensor specifically to be a temperature sensor. Tu, et al., however, discloses a radio frequency ablation probe with a temperature sensor 27 adjacent to the distal end of the electrode needle (Fig. 6). The addition of a temperature sensor is advantageous because it allows the radio frequency output to be precisely controlled to obtain the desired temperature for treating a tissue (col. 4, ln. 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal sensor of Abele to be a temperature sensor in view of the teachings of Tu, et al. for the advantage of precisely

controlling the radio frequency output to obtain the desired temperature for treating a tissue.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran in view of Abele.

Imran discloses an electrode for a probe in accordance with claims 1 and 9 wherein the micro-cuts extend parallel to one another. The claim differs from Imran in calling for the micro-cuts to be formed in a spiral shape, a meander shape, a wave shape, or a zig-zag shape in a middle section. Abele, however, teaches an electrode in accordance with claim 1 whose flexible electrode arms are wave shape in a middle section to "maximize the wire contact coverage when the basket is expanded" (col. 4, ln. 11-12 and Figs. 12 and 13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the micro-cuts of Imran in a wave shape in view of the teachings of Abele in order to maximize the wire contact coverage when the electrode is expanded.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon rejected base claims 1 and 9, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 4,699,147 to Chilson, et al.
U.S. Pat. No. 5,100,423 to Fearnot

U.S. Pat. No. 5,471,982 to Edwards
U.S. Pat. No. 5,496,330 to Bates, et al.
U.S. Pat. No. 5,725,525 to Kordis
U.S. Pat. No. 5,738,683 to Osypka

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
7/14/05

MICHAEL PEFFLEY
PRIMARY EXAMINER